

which had also been injected with TRIS buffer retained a normal health appearance including their rectums. Their occult blood stool samples were still negative and there were no rectal exudates detected. Their weight increased from 17.1 to 19 grams and 17.4 to 18.7 grams.

### 3. Amelioration of Signs or Symptoms of Attributable to Inflammatory Bowel Disease

A human patient having IBD is treated with the invention. In particular, the patient has symptoms which may include diarrhea, abdominal pain, fever, melena, hematochezia, and weight loss and signs which may include abdominal mass, glossitis, aphthous ulcer, anal fissure, perianal fistula, anemia, malabsorption, and iron deficiency. The patient is initially treated with five  $\mu$ g of IL-10 per kilogram body weight per day. Because the patient weighs 70 kg, the initial starting dose is 350  $\mu$ g per day of IL-10. This dose is administered as an intravenous bolus. The dose is increased by about 50 to 150  $\mu$ g per day depending on the patient's tolerance and response. An optimum dose of about 700  $\mu$ g per day (10  $\mu$ g per kilogram per day) is achieved after several days.

Prior to the first treatment, and daily thereafter until several days after the final treatment, the patient is monitored clinically and with laboratory parameters. The laboratory parameters include blood counts with particular attention to the total white blood cell count and its differential. Of special interest is whether the amount of white cells remains normal or without significant change from the patient's pre-treatment level. With respect to the white cell differential, particular attention is given to whether immature forms are appearing in the peripheral blood and whether the normal ratio of different types of white cells is constant or changing. Special attention is paid to the ratio of lymphocytes and monocytes in the peripheral blood.

Additional parameters which can be monitored include the erythrocyte sedimentation rate (ESR), chemical profiles, blood levels of IL-6, TNF and IFN- $\gamma$ . Finally, regular, such as daily, evaluation of the patient's stool for blood and purulent exudate can indicate the patient's response to therapy.

All of the references referred to herein are incorporated by reference. Additionally, other aspects of the invention will be readily apparent to those of ordinary skill in the art. Thus, the invention is not limited by the preceding description and examples, but rather by the claims that follow.

What is claimed is:

1. A method of treating an inflammatory bowel disease in a mammal comprising:

administering to the mammal an effective amount of IL-10.

2. The method of claim 1 wherein the inflammatory bowel disease is Crohn's Disease.

3. The method of claim 1 wherein the inflammatory bowel disease is ulcerative colitis.

4. The method of claim 1 wherein the administration is parenteral.

5. The method of claim 4 wherein the parenteral administration is intravenous.

6. The method of claim 1 wherein the effective amount is selected from a range of about 1 microgram to about 100 milligrams per kilogram of body weight.

7. The method of claim 6 wherein the effective amount is selected from a range of about 10 micrograms to about 1000 micrograms per kilogram of body weight.

8. The method of claim 6 wherein the effective amount is selected from a range of about 50 micrograms to about 100 micrograms per kilogram of body weight.

9. The method of claim 1 wherein the mammal is a human.

10. The method of claim 4 further comprising using combination therapy including co-administration of effective amounts of IL-10 and at least one additional therapeutic agent.

11. The method of claim 10 wherein the additional therapeutic agent is selected from a group consisting of corticosteroids, sulphasalazine, cyclosporin A, mercaptopurine, and azathioprine.

12. The method of claim 10 wherein the co-administration is sequential.

13. The method of claim 10 wherein the co-administration is simultaneous.

14. A method of predicting a mammal's predisposition for development of an inflammatory condition associated with inflammatory bowel disease characterized by suboptimal levels of IL-10 comprising:

1) assaying a sample taken from the mammal for an IL-10 level and 2) comparing the IL-10 level in the sample to a known normal value of IL-10.

15. The method of claim 14 wherein the sample is blood.

16. The method of claim 14 wherein the inflammatory condition is selected from a group consisting of an inflammatory bowel disease, an anemia associated with an inflammatory bowel disease, an arthritis associated with an inflammatory bowel disease, and a dermatitis associated with an inflammatory bowel disease.

17. The method of claim 16 wherein the inflammatory bowel disease is selected from a group consisting of ulcerative colitis and Crohn's Disease.

18. A pharmaceutical composition for administration to a mammal having an inflammatory bowel disease comprising:

an effective amount of IL-10 to ameliorate at least one of a symptom or a sign of the inflammatory bowel disease in the mammal; and

a pharmaceutically acceptable additive.

19. The composition of claim 19 wherein the amount of IL-10 is selected from a range of about 1 microgram to about 100 milligrams per kilogram of body weight of the mammal.

20. The composition of claim 18 wherein the composition is in a form suitable for parenteral administration.

21. The composition of claim 18 wherein the pharmaceutically acceptable additive is an aqueous vehicle.

22. The composition of claim 18 wherein the effective amount is a unit dose presented in an ampoule.

23. The composition of claim 18 wherein the inflammatory bowel disease is selected from a group consisting of ulcerative colitis and Crohn's Disease.

24. The composition of claim 18 wherein the symptom is selected from a group consisting of diarrhea, abdominal pain, fever, melena, hematochezia, and weight loss.

25. The composition of claim 18 wherein the sign is selected from a group consisting of abdominal mass, glossitis, aphthous ulcer, anal fissure, perianal fistula, anemia, malabsorption, and iron deficiency.

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